DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

G4316d

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

September 25, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jacqueline Kocz
Executive Director, Community Blood Bank of Erie
2646 Peach Street
Erie, Pennsylvania 16505

Dear Ms. Kocz:

During the inspection of your facility, Community Blood Bank of Erie, 2646 Peach Street, Erie, Pennsylvania, June 2-13 and June 17-18, 2003, our investigator documented numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (CFR), Parts 211 and 606. These deviations cause your facility to be in violation of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The deviations observed include the following:

1. Failure to maintain written standard operating procedures that include the steps to be followed in the collection, processing, storage, and distribution of blood and blood components [21 CFR § 606.100(b)], for example:

    a. There is no written procedure for blood bank laboratory's practice of manually adding acid to specimen wells during automated viral testing runs.

    b. There is no written procedure that defines parameters to be used by the laboratory to determine when a viral test run is considered invalid or when it can be re-run based on an Unusual Occurrence.

    c. There is no written procedure for the donor center's practice of obtaining and reading two hematocrit capillary tube samples from donors and documenting the average of the two values on the donor history card.

2. Failure to follow written standard operating procedures, including all steps to be followed in the processing of blood and blood components [21 CFR 211.100(b)], for example:

    a. Failure to repeat test unit [redacted] in duplicate after testing HBc(core) initially reactive on 12/5/01, tray #[redacted].

b. Failure of laboratory personnel during viral testing to generate the plate map prior to the initial incubation as required by blood bank standard operating procedures.

c. Failure to conduct blood component inventory audits on a quarterly basis as required by blood bank standard operating procedures.

d. Failure to review completed competency assessment of laboratory employees as required by blood bank standard operating procedures.

e. Failure to have the blood bank physician review donor reaction forms to determine future donor suitability when donor reactions have been classified as severe as required by blood bank standard operating procedures.

f. Failure to complete equipment maintenance log, and maintain quality control data for recorded user problems and periods when out-of-service for [redacted] Hematology Analyzer in accordance with blood bank standard operating procedures. Also, the [redacted] quality control log does not include the serial number of the instrument being calibrated.

g. Expiration date of controls used in the [redacted] Hematology Analyzer is not documented between 5/5/03 through 5/14/03.

3. Failure to maintain complete, accurate, or concurrent records with the performance of each significant step in the collection, processing, storage, and/or distribution of each unit of blood so that all steps can be clearly traced; and, failure of all records to be indelible [21 CFR § 606.160(a)(1)], in that, Washed Red Blood Cell Logs for 1/2/2002 – 1/30/2002 and 1/17/2003, for units [redacted] do not document a time of preparation, and, do not document the expiration date and time. Also, Washed Red Blood Cell Log documentation that is available for these units is in pencil.

4. Failure to exercise appropriate controls over computers or related systems to assure that changes in records are instituted only by authorized personnel [21 CFR § 211.68(b)], in that, passwords for the blood bank computer system have not been changed since the initiation of the system in December 1997, and there is no documented authorization for modem access for log-ins and log-outs dated 1/8/02, 1/11/02, 1/25/02, and 4/24/03.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. As management it is your responsibility to ensure that your establishment is in compliance with all requirements of federal regulations as well as all other requirements of the FD&C Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

We acknowledge receipt of your letter dated July 28, 2003, which proposes corrective actions to the Inspectional Observations noted on Form FDA-483 issued on June 18, 2003. We offer the following comments:

1. Your response to observation 1(a) states, "The [redacted] viral system is a semi-automated system that allows for manual steps to be taken during the performance of the testing. All manual acid additions were within the systems specified time frames, read within the appropriate time frame, and documented according to SOP." Your response to observation 1(b) states, "An SOP titled: "Unusual Occurences in Viral Testing" has been written and implemented that addresses invalidation and reread of viral testing." Our review finds these responses incomplete in that you failed to provide documentation to demonstrate that SOPs have been appropriately revised, procedures have been validated, and employees have been trained on the revised procedures. In addition, we suggest you reference all applicable viral marker package inserts and FDA's most recent guidance on invalidation of test results, "Guidance For Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors," July 11, 2001. [http://www.fda.gov/cber/guidelines.htm]

2. Your response to observation 2(a) states, "the SOP for viral testing states that times and temperatures will be documented on the plate map, not that the plate map will be generated prior to initiating the incubation of trays." Our review finds this response inaccurate. If the viral testing SOPs (HIV-1/HIV-2 EIA, HCV, HBsAg, HTLV I & II, Corzyme, and HIVAg-1) are followed in sequence, the plate map should be generated prior to incubation, eliminating the need to record the initial incubation time on a scrap paper and subsequently transfer the time onto the plate map. Otherwise, the SOP should be revised to reflect the use of a worksheet to concurrently document incubation times and temperatures. 21CFR § 606.160(a)(1) requires that all "critical steps" in donor testing for hepatitis, HIV, and HTLV-I/II be concurrently documented in order to document that procedures were followed according to manufacturer's directions. Critical steps include, but are not limited to incubation times, the preparation and addition of [redacted], the addition of acid to stop color development, as well as the final read time of the test trays.

3. Your response to observation 2(b) states, "Inventory audits will be performed in the future according to SOP." Our review finds this response appropriate pending confirmation of compliance during the next inspection.

4. Your response to observation 3(a) states, "An SOP regarding computer access and safety has been written and includes directions regarding password changes." Our review finds this response incomplete in that you failed to provide documentation to demonstrate that SOPs

have been appropriately revised, procedures have been validated, and that employees have been trained on the revised procedures.

5. Your response to observation 3(b) states, "After the inspectors had completed the inspection, we received documentation from [redacted] of modem access for the dates in question. Future e-mails regarding modem access will be printed and saved." Our review finds this response incomplete in that you failed to provide documentation to demonstrate that an SOP has been written detailing modem access authorization, that the procedures have been validated, and that employees have been trained on the procedure.

6. Your response to observation 4 states, [redacted] system is a user-defined blood bank computer system. The Product Safety Advisories in question pertained to modules not used by Community Blood Bank as was documented on the forms." Our review finds this response appropriate pending confirmation of compliance during the next inspection.

7. Your response to observation 5 states, "the SOP 'Recording and Follow Up of Donor Reactions' has been revised to include more detail for determining the severity of a reaction. The Medical Director will evaluate severe reaction documentation prior to the donor being reinstated. The form relating to this SOP will be revised to include an area for Medical Director documentation." Our review finds this response incomplete in that you failed to provide documentation to demonstrate that SOPs have been appropriately revised, procedures have been validated, and that employees have been trained on the revised procedures.

8. Observations 6 (a, b, d & g). Our review finds these responses incomplete in that you failed to provide documentation to demonstrate that SOPs have been appropriately revised, procedures have been validated, and that employees have been trained on the revised procedures.

9. Your response to observation 6(c) states, "All pencil entries referred to in this area were found on other processing sheets after the inspection had ended." This observation remains a deviation of 21 CFR § 606.160(a)(1).

10. Your response to observation 6(e) states, "Annual review forms were reviewed and signed." Your response to observation 6(f) states, "The [redacted] equipment maintenance will be documented according to the Equipment Maintenance SOP." Our review finds these responses appropriate pending confirmation of compliance during the next inspection.

11. Observation 7 & 8. Our review finds these responses incomplete in that you failed to provide documentation to demonstrate that SOPs have been appropriately revised, procedures have been validated, and that employees have been trained on the revised procedures.

12. Discussion item 1 relates to your use of previously tested donor samples as negative external controls. We suggest you review your procedures for obtaining negative external controls and determine their qualifications prior to use. Donor samples that test initially reactive for viral marker tests, whether or not their intended use is for a control, should be repeat tested in duplicate, and appropriate donor deferral, quarantine, and lookback procedures be performed.

We request that you notify this office in writing within (15) working days of receipt of this letter of all specific actions that have been implemented to correct the noted violations. Your response should include copies of updated written procedures, verification of the training of personnel, and an explanation with verification of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Philadelphia District Office, Room 900, U. S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106, to the attention of William J. Forman, Compliance Officer.

Sincerely,

Thomas D. Gardine

Thomas D. Gardine
District Director
Philadelphia District

Attachments:

FDA-483, Inspectional Observations, dated, 7/20/01 & 8/15/00.

PDH Bureau of Laboratories
Blood Bank Division
Pickering Way & Welsh Pool Road
Lionville, Pennsylvania 19341